

**DETAILED ACTION**

1. This action is in response to Applicant's correspondence dated November 9, 2007.

Claims 1 and 3-24 are currently pending and under examination.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Examiner previously rejected claims 1-2, 8, 11-12 and 19-24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Examiner withdraws his previous rejection of claim 1 due to Applicant's claim amendments.

(b) Examiner withdraws his previous rejection of claim 2 because this rejection is now moot as Applicant cancelled claim 2.

(c) Examiner withdraws his previous rejection of claim 8 due to Applicant's claim amendments.

(d) Examiner withdraws his previous rejection of claim 11 due to Applicant's claim amendments.

(e) Examiner withdraws his previous rejection of claim 12 due to Applicant's claim amendments.

(f) Examiner withdraws his previous rejection of claims 19-24 due to Applicant's claim amendments.

(g) Examiner withdraws his previous second rejection of claim 19 due to Applicant's claim amendments.

(h) Examiner withdraws his previous rejection of claim 21 due to Applicant's claim amendments.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Examiner previously rejected claims 1-3, 5, 7, 11-12 and 15-17 under 35 USC 102(b) as being anticipated by Shafiee, et al., WO 96/12492. Examiner withdraws these rejections due to Applicant's claim amendments.

***Claim Objections***

5. Examiner previously objected to claims 4, 6, 9-10, 13-14 and 18 as being dependent upon rejected independent claim 1. Examiner withdraws these objections due to Applicant's claim amendments.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 8, 10-11 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The following apply.

(a) "Nitrogen-containing aromatic compound" of claim 8 and "pyridine derivative" of claim 10 are unclear as a reader would not necessarily understand what is included and what is excluded by these terms as they do not sufficiently describe chemical structure. Clarification is required.

(b) What is intended by "raw material" of claim 11? This rejection can be obviated by deleting "is used as a raw material" from the claim.

(c) The solvent containing 50 wt% or more of water limitation of claim 16 lacks antecedent basis because claim 1 limits the organic solvent to possess a water content of 15 wt% or less. Correction is required.

***Claim Rejections 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 5-6, 21 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wu, et al., U.S. Patent Publication 2003/208074. The reference teaches various processes of alkylating chiral 2-methyl-4-protected piperazine compounds, which includes a very similar process to the instant processes. Specifically, note process Example 2, beginning on column 7 of the reference when R<sup>2</sup>, R<sup>3</sup> and R<sup>4</sup> are all hydrogen, R<sup>1</sup> is alkyl (methyl) and X is benzyl.

Merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of unexpected results. *In re Aller*, 220 F.2d 454, 105 USPQ 233 (CCPA 1955). As such, even though the weight percent of the organic solvent in Example 2 is 15.8% (it states 1200 mL of methanol and 400 mL of water), it would have been obvious for Applicants to slightly change the weight percent of the solvent of the reference in hopes of achieving a purer product or one of greater yield.

Therefore, the instant claims 1, 3, 5-6, 21 and 23 are rendered obvious by Wu, et al., U.S. Patent Publication 2003/208074.

Claims 1 and 3-6, are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kim, et al., *N-Benzyloxycarbonyl-2-methylaminothiazoline as a Selective Benzyloxycarbonylating Reagent of Amines*, Bull. Korean Chem. Soc., Vol. 24, No. 2, 157-58 (2003). The reference teaches various processes of benzyloxycarbonylating amines, which includes a very similar process to the instant processes. Specifically, it would have been obvious to one skilled in the art when the invention was made to combine Scheme 2 and Scheme 3 of the reference to arrive at the instant process when R<sup>2</sup>, R<sup>3</sup> and R<sup>4</sup> are all hydrogen, R<sup>1</sup> is alkyl (methyl) and X is benzyl chlorocarbonate.

The organic solvent claim limitation is met by the reference because the organic solvent used in the process of the reference uses ethanol that is similar to most available on the market, which have a weight percent of water which is 15% or less. See Biochemicals & Reagents for Life Science Research (2004-2005) by Sigma.

Therefore, the instant claims 1 and 3-6 are rendered obvious by Wu, et al., U.S. Patent Publication 2003/208074.

### ***Claim Objections***

Claims 7, 9, 19-20, 22 and 24 are objected to as being dependent upon rejected independent claim 1, but would be allowable if rewritten in independent form.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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